



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

## In re Application of:

Artman et. al.

Serial No.: 10/614,344

**Filed:** July 8, 2003

For: TREATING A VARIETY OF PATHOLOGICAL CONDITIONS, INCLUDING SPASTICITY AND CONVULSIONS, BY EFFECTING A MODULATION OF CNS ACTIVITY WITH ISOVALERAMIDE, ISOVALERIC ACID, OR A RELATED COMPOUND

Confirmation No.: 7848

Examiner: D. Claytor

Group Art Unit: 1617

Attorney Docket No.: 1959-7467.1US

(N-405US-DIV)

Notice of Allowance Mailed:

March 26, 2007

#### NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EV962535844US

Date of Deposit with USPS: June 22, 2007

Person making Deposit: \_\_\_\_ Cat Bratton

# **COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE**

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This communication is filed in response to the Notice of Allowance mailed March 26, 2007 and sets forth Applicants' comments, pursuant to 37 C.F.R. §1.104(e), on the

Examiner's Statement of Allowable Subject Matter accompanying the Notice of Allowance.

### In the Office Action dated February 7, 2005, the Examiner indicates:

Claims 37 and 39 are allowed, because the prior art does not teach or reasonably disclose methods of treating convulsions and headaches in patients in need thereof by administering effective amounts of isovaleramide.

### <u>In the Notice of Allowance dated March 26, 2007, the Examiner indicates:</u>

The claimed invention is drawn to a method of treating a convulsive disorder comprising administration of isovaleramide to a patient suffering from a convulsive disorder, wherein the convulsive disorder is selected from the group consisting of simple partial seizures, complex partial seizures, generalized tonic-clonic seizures, secondarily generalized seizures, status epilepticus and trauma-induced seizures and a method of treating headaches comprising administration of isovaleramide. Applicant teaches that the administration of isovaleramide decreases the expression of amygdala-kindled seizures in fully kindled rats (Examples 5 and 6). The closest prior art is Balandrin et al. (U.S. Patent 5,506,268), Drug Facts and Comparisons 1999 ed. Pgs. 1595-1597, and Pharmacotherapy, A Pathophysiologic Approach (Dipiro et al. 2<sup>nd</sup> ed. Elsvier, 1991, pgs. 132 and 1238).

Balandrin et al. teach isovaleramide as an effective anxiolytic agent that decreases spontaneous locomotor activity but does not teach that isovaleramide decreases convulsive disorders. Drug facts teaches that diazepam is an anxiolytic that is an anti-convulsant to treat status epilepticus and recurrent convulsive seizures but does not teach anything about isovaleramide. The above mentioned prior art does not teach the use of isovaleramide to treat convulsive disorders selected from the group consisting of simple partial seizures, complex partial seizures, generalized tonic-clonic seizures, secondarily generalized seizures, status epilepticus and trauma-induced seizures; therefore, the use of isovaleramide for the treatment of convulsive disorder is novel and non-obvious. Further, Pharmacotherapy teaches that headache is a symptom associated with premenstrual syndrome. It is also taught that a known anxiolytic agent, alprazolam, is useful in treating premenstrual syndrome but there is no teaching of isovaleramide. Because the prior art does not teach the use of isovaleramide for the treatment of headaches, it is therefore novel and non-obvious.

Applicants concur with the reasons as stated by the Examiner insofar as they comprise a summary, which is exemplary and not limiting. However, the scope of the claims is based on the actual language of the claims and equivalents thereof, and not on a paraphrase or summary of the claim language.

The Independent claims as allowed recite features and methodology in addition to, and in different language than, those described in the Statement of Allowable Subject Matter.

Furthermore, the dependent claims recite elements in addition to those of the independent claims, which are also not reflected in the Statement of Allowable Subject Matter. Such additional elements, in combination with those of the independent claims from which each claim depends, provide additional reasons for patentability. Accordingly, the scope of the claims must be determined from the literal language of each as a whole, as well as all equivalents thereof.

Therefore, to the extent that the Examiner's reasons for allowance as stated are not relevant to, or wholly encompassing of, a particular claim, independent or dependent, Applicants assume that (pursuant to 37 C.F.R. §1.104(e)) the Examiner has determined that the record of the prosecution as a whole of the application makes clear the reasons for allowing those claims. Further, it appears, pursuant to M.P.E.P. 1302.14, that the Examiner's Statements of Allowable Subject Matter are not intended to encompass all of the reasons for allowance.

Respectfully submitted,

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Date: June 22, 2007

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